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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,985	09/25/2003	Jaime L. Rugnetta	279.607US1	4509

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EXAMINER	
KRAMER, NICOLE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/670,985	**Applicant(s)** RUGNETTA ET AL.	
	Examiner Nicole R. Kramer	**Art Unit** 3762	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 October 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached Responses to Arguments.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The proposed amendments filed 10/13/06 will not be entered because they present additional claims (new claims 21-25) without canceling a corresponding number of finally rejected claims.

2. However, Examiner notes that the amendments to claim 8 would be entered after-final if a separate paper were filed containing only such amendments. See MPEP 714.13. Such amendments are believed to overcome the 112 rejection set forth in the Final Office Action of 6/13/06, and thus place the application in better condition for appeal.

Response to Arguments

3. Applicant's arguments filed 10/13/06 have been fully considered but they are not persuasive.

4. More specifically, Applicant argues that Huenpenbecker does not teach a recessed portion recessed away from the bottom of the tine when the tine is disposed in a second collapsed position. In support of such an argument, Applicant notes that Huenpenbecker does not include any figures illustrating tines in a collapsed position. Applicant argues that there is no disclosure in Huepenbecker of the tines collapsing, and no disclosure of the tines being recessed away from a first recessed portion (see page 9 of Response filed 10/13/06).

As explained in the Final Rejection mailed 6/13/06, ***although not explicitly stated in Huenpenbecker***, passive tines such as the ones illustrated in Huenpenbecker are necessarily are formed of a flexible material such that the tines fold/collapse against the lead body during insertion into the patient. In the Final Rejection, Examiner cited numerous patents to support this assertion (see, for example, U.S. Patent No. 5,531,781 to Alferness which teaches that tines are formed as flexible and pliant such that they collapse and do not interfere with or impede steering during implantation of the lead; see col. 6, lines 35-40. See also U.S. Patent No. 5,571,157 which describes that tines flatten against the lead body thus reducing its diameters such that the tined lead is suitable for introduction through small blood veins; see col. 1, lines 45-55. In addition, see U.S. Patent No. 4,409,994 which teaches foldable tines which collapse against the lead body recessed portion during implantation of the lead). In order to implant the lead distal end at the heart such that it can provide the desired pacing or defibrillation therapy, the tines necessarily must fold down/collapse against the lead body such that the lead can be tracked through a patient's vasculature system to the implantation site of the right ventricular apex (see col. 2, line 59). When the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine because the bottom surface of tines would contact the outer surface of sleeve 36 (which forms the second recessed portion), thus leaving the first portion (which is illustrated as smaller in cross-section than the second recessed portion) recessed away from the bottom surface of the tine.

5. In addition, Applicant argues the statement made in the Office Action that Figure 4 of Huenpenbecker illustrates that the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion (see pages 10-11 of Response filed 10/13/06) because Figure 4 illustrates the cross-section of the lead taken only along a single axial plane. Since the axial view of Figure 4 shows the diameter of the first recessed portion to be smaller than the diameter of the second recessed portion, Examiner maintains the position of the Final Office action mailed 6/13/06.

6. With respect to claim 4, Applicant's argues that since Huenpenbecker does not state that the drawings are to scale, the Figure 4 of Huenpenbecker cannot anticipate the claim 4 of the present invention (see page 10 of Response filed 10/13/06). Claim 4 requires that the first cross-section area (at the tine interface section) be less than 10% smaller than the second cross-sectional area (which is defined as a second area between the tine and the lead distal end). "Less than 10% smaller" includes areas that are between 1-9% smaller, as well as equal areas or areas that larger than the second area. Examiner maintains that Figure 4 illustrates that the cross-sectional area at the lead distal end (between electrode 38 and the tine- coupling portion) is approximately the same as the cross-sectional area of the tine coupling portion. As such, the cross-sectional area of the tine coupling area is approximately equal to the cross-sectional area of the lead distal end, and thus necessarily "less than 10% smaller" than the cross-sectional area of the lead distal end.

7. Applicant also argues that Laske does not teach a recessed portion recessed away from the bottom of the tine when the tine is disposed in a second collapsed position (see pages 11-12 of Response filed 10/13/06). In support of such an argument, Applicant notes that Laske does not include any figures illustrating tines in a collapsed position. Applicant argues that there is no disclosure in Laske of the tines collapsing, and no disclosure of the tines being recessed away from a first recessed portion.

As explained in the Final Rejection mailed 6/13/06, ***although not explicitly stated in Laske***, tines such as the ones illustrated in Laske are necessarily are formed of a flexible material such that the tines fold/collapse against the lead body during insertion into the patient. In the Final Rejection, Examiner cited numerous patents to support this assertion (see, for example, U.S. Patent No. 5,531,781 to Alferness which teaches that tines are formed as flexible and pliant such that they collapse and do not interfere with or impede steering during implantation of the lead; see col. 6, lines 35-40. See also U.S. Patent No. 5,571,157 which describes that tines flatten against the lead body thus reducing its diameters such that the tined lead is suitable for introduction through small blood veins; see col. 1, lines 45-55. In addition, see U.S. Patent No. 4,409,994 which teaches foldable tines which collapse against the lead body recessed portion during implantation of the lead). More specifically, Laske incorporates by reference U.S. Patent No. 3,902,501 to Citron et al., which teaches that the tines fold/collapse against the lead body during insertion into the patient (see Figures 6 and 11 of Citron et al. and associated text). In order to implant the lead distal end at the

heart such that it can provide the desired pacing therapy, the tines necessarily must fold down/collapse against the lead body such that the lead can be tracked through a patient's vasculature system to the implantation site of the endocardium. When the tines collapse during implantation, the first recessed portion would necessarily be recessed away from the bottom surface of the tine because the bottom surface of tines would contact the outer surface lead body (which forms the second recessed portion), thus leaving the first portion or groove 152 (which is illustrated as smaller in cross-section than the second recessed portion) recessed away from the bottom surface of the tine.

8. In addition, Applicant argues the statement made in the Office Action that Figure 5 of Laske illustrates that the cross-sectional area of the first recessed portion is smaller than the cross-sectional area of the second recessed portion (see pages 12-13 of Response filed 10/13/06) because Figure 5 illustrates the cross-section of the lead taken only along a single axial plane. Since the axial view of Figure 5 shows the diameter of the first recessed portion to be smaller than the diameter of the second recessed portion, Examiner maintains the position of the Final Office action mailed 6/13/06.

9. With respect to claims 2, 5, 11, 13, and 17-18, Applicant next argues that the motivation statement to combine Huenpenbecker (or Laske) and Alferness et al. is unsupported by the references. As stated in the Final Rejection mailed 6/13/06, the motivation to combine the references (to ensure that the lead body is sufficiently strong

during implantation) is based on common sense and in the knowledge generally available to one of ordinary skill in the art. Alferness is directed to an implantable lead having a steerable tip at the distal end of the lead such that the lead can be steered along a desired path as the lead is implanted (see, for example, Alferness at col. 1, lines 8-15). The lead must be sufficiently strong to be tracked/maneuvered around corners, past branches, and across constrictions (see Alfterness at col. 1, lines 56-67). Thus, Alferness teaches the necessity and desirability of ensuring that the lead body is sufficiently strong during implantation. Further, Examiner maintains that added material in the area of the recesses 167, as shown in Figure 10 of Alferness et al., would necessarily strengthen the lead body at the distal end thereof such that it is sufficiently strong to be tracked through a patient's vasculature system to the implantation site of the endocardium.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRK
10/17/06

George Manuel
Primary Examiner